K013709

Hill-Rom
A HILLENBRAND INDUSTRY

510(k) Summary
Date: September 12, 2001

NOV 1 6 2001

1. Establishment Information:

Submitter:	Hill-Rom A Hillenbrand Industry 1069 State Route 46 East Batesville, IN 47006-9167
Registration #:	1824206 (Owner/Operator) 1836145 (Manufacturing Site)
Contact Name:	Timothy M. Davis
Contact Phone #:	812-931-3825 or 1-800-445-2114 (x-13825)
Contact Fax #:	812-934-1675

2. General Device Information:

Common Name:	Video Display (No Audio)
Trade Name:	Hill-Rom PrimaView Monitor System
Classification Name:	Endoscope and accessories
Classification Number:	876.1500 (accessory item – monitor)
Device Classification:	Class II
Performance Std:	Performance Standards for this device have not been established under section 514 of the FD&C Act.

3. Substantial Equivalence: Hill-Rom PrimaView Monitor System is substantially equivalent in the intended use (display video images) to the Sony Trinitron Color Video Monitor PVM-1343MD cleared under 510(k) number K885042.

4. Technology Differences: The primary difference between the predicate device and the Hill-Rom PrimaView Monitor System is that the display on the Sony Trinitron Monitor is CRT based and the PrimaView uses LCD flat screen technology. The Sony system also is a portable device (stand-alone), whereas the PrimaView is a fixed surgical mounted display that uses interconnecting hardware and circuitry to route the video signal. However both devices are designed to accept various types of signals (analog and digital) from Endoscopic, Laproscopic or other similar sources for display.

5. Device Description: The Hill-Rom PrimaView Monitor System is considered an accessory item to an endoscopic or laproscopic system (not supplied by Hill-Rom) in that it provides a means to view images generated by an endoscopic or laparoscopic camera and their associated components. The PrimaView flat screen display is mounted in the operating room or other area of a medical facility where endoscopic or similar procedures are done. Output video signals from the camera and processing unit are fed into the appropriate input connector of the PrimaView System. The signal

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is then routed to the display for presentation to the clinician. The system can also be used to display reference quality (not for diagnosis) radiographic images

6. Intended Use: The Hill-Rom PrimaView Monitor System is indicated for use in providing the clinician with a color video display of images that are generated from endoscopic, laparoscopic or similar equipment (not supplied by Hill-Rom) during surgical procedures. This system may also be used to display radiographic images for reference only.

7. Performance Data: Compliance to all or applicable parts of IEC, EN, CISPR, UL and CSA standards (IEC 601-1-2, EN 60601-1 and -2, EN 61000-4-3,4,5, CISPR 11, UL 2601-1 and CSA C22.2 601.1-M90) will be confirmed through design testing and documented. Documentation will be retained in the design and development file as part of the Design History File (DHF).

8. Conclusion: The Hill-Rom PrimaView Monitor System is designed to be safe and effective for its intended use. Verification and Validation Testing will be completed prior to commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Hill-Rom, Inc.
c/o Ms. Chantel Carson
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, Illinois 60062

NOV 1 6 2001

Re: K013709
Trade/Device Name: Hill-Rom PrimaView Monitoring System
Regulation Number: 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: November 6, 2001
Received: November 8, 2001

Dear Ms. Carson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

"Indications for Use Statement"

NOV 1 6 2001

510(k) Number (if known): K013709

Device Name: Hill-Rom PrimaView Monitoring System

Indications For Use:

The Hill-Rom PrimaView Monitor System is indicated for use in providing the clinician with a color video display of images that are generated from endoscopic, laproscopic or similar equipment (not supplied by Hill-Rom) during surgical procedures. This system may also be used to display radiographic images for reference only.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF REQUIRED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over-The Counter Use: _____
(21 CFR 801.109)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013709